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PRINCIPAL INVESTIGATOR:

Rena J. Pasick, Ph.D.

CONTRACTING ORGANIZATION: Northern California Cancer Center

Union City, California 94587

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E-Mail: rpasick@nccc.org				
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BACCIS-II, is a randomized controlled trial of an outreach intervention designed to increase the rate of periodic mammography among underserved women. The purpose was to assess the feasibility and cost-effectiveness of BACCIS-II, a moderate level of intervention, compared retrospectively with the more intensive predecessor, BACCIS, and compared with a minimal (control group) intervention. In BACCIS-II, women in low-income communities are encouraged to become "links" to the community to identify women ages 45+ with no mammogram past two years, and to provide their names to project staff. Women were then called by part-time staff who offered education, motivation and assistance in obtaining screening. Only 346 women were recruited by links, a number far short of our goal indicating low feasibility of the model. Outcome data are available for 60% of the sample who could be recontacted 14- 25 months after recruitment for a telephone survey. A significantly higher proportion of women in the intervention group received a mammogram since baseline (83% vs 67%, p=0.02) despite the fact that women in the intervention group reported significantly lower income (p<.05) and had less health insurance (p<0.0001). We conclude that outreach to underserved women remains time-consuming and costly. However, personal contact by trusted others is effective in motivating and assisting women to obtain initial and repeat screening.

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### I. INTRODUCTION

### A. Subject, Purpose and Scope of this Research

The study "Breast Cancer Outreach for Underserved Women: A Randomized Trial and Cost-Effectiveness Analysis," *BACCIS-II*, <sup>1</sup> addresses two major gaps in the current state of knowledge for breast cancer outreach to underserved women: 1) absence of affordable, cost-effective interventions, and 2) interventions specifically intended to improve lifelong, periodic early detection practices, as distinct from only initial or one-time screening. In BACCIS-II, a moderate level outreach intervention (which retains the key strengths of more intensive original BACCIS, including woman to woman contact by trusted others from within the community and contact that is sustained over time to support and reinforce repeat screening) is tested for feasibility and cost-effectiveness in comparisons with a more intensive outreach intervention (the original BACCIS) and a minimal intervention (control group).

### The research hypotheses include:

- 1. Women reached through the moderate, adapted intervention will make significantly greater advances in screening adoption stage than will women reached by the minimal intervention.
- 2. The moderate intervention will be more cost-effective than either the intensive or minimal interventions.
- 3. The moderate, adapted intervention will be shown to be feasible and appropriate in low-income and multi-ethnic communities.
  - a. Businesses/agencies/organizations located in and/or serving low-income communities can be recruited to participate in training and to otherwise support outreach to women at risk of late stage diagnosis.
  - b. Early detection knowledge and outreach/education skills of trainees will be significantly higher at the end of the training compared with initial levels prior to training.
  - c. Trainees will reach target numbers of underserved/under screened women and complete outreach and follow-up.

### The specific aims of this study are:

- 1. To test the feasibility and effectiveness of a generalizable, moderate intensity early breast cancer detection outreach model.
  - a. adapt the original BACCIS outreach model for appropriateness to, and use by agencies located in and traditionally serving low-income, multi-ethnic communities.
  - b. over 12 months, recruit 20 businesses/ agencies/ organizations in low-income

<sup>&</sup>lt;sup>1</sup>The acronym "BACCIS-II" is derived from the predecessor to this research, the "Breast and Cervical Cancer Intervention Study", BACCIS, funded by the National Cancer Institute, 1991-1997. In the community, we have adapted our title and call the program the *Breast Cancer Community Information and Screening* project. In the research arena, we refer to it as BACCIS-II.

neighborhoods to commit 80 workers/residents (4 per agency) to be trained to meet standards for knowledge, commitment, and skills in cancer screening outreach, education, resource referral, and follow-up.

- c. Reach 1600 underserved (defined here as those who have inadequate or no health insurance and/or women of color), under screened (for women 50 and over, no mammogram in past two years; for women ages 40 and over, no clinical breast exam in past two years) who, as a direct result of BACCIS-II, will demonstrate significant advances in adoption stage for mammography, clinical breast exam, and breast self-exam:
  - For women 40-49, this means received the overdue CBE, discussed mammography with provider, reports intention to obtain mammography in the future and to repeat screening throughout life, and demonstrates knowledge of how to obtain testing.
  - For women 50+, this means received overdue mammogram/CBE, reports intention to repeat annual tests throughout life, and demonstrates knowledge of how to obtain testing.
  - For all women, adherence to BSE will mean monthly testing for at least the past three months, report of having had instruction in the correct methods, and intent to continue BSE throughout life.
- 2. To evaluate the cost-effectiveness per woman who increases her level of adherence in the intensive, moderate, and minimal interventions.
  - From a societal perspective that takes into account all costs and benefits regardless of who pays or receives them.
  - From an organizational perspective that includes only actual financial costs to the organization implementing the intervention.

The original research plan called for recruitment and randomization of 3200 women over a three year period. Due to much slower than anticipated recruitment (a function of the less intensive outreach model), the sample size was reduced to 1000 and then to 500 (revised Statements of Work were approved).

### II. BODY OF REPORT

### A. Technical Objectives: To test the feasibility and effectiveness of a moderate intensity outreach intervention

### (ii.) Update

Because of slow recruitment, the trial was temporarily halted in October 1998 in order to modify the intervention model and to conduct a pilot test of the modified model. The trial resumed in December 1998 with improved recruitment, although still not on course for attainment of sample size objectives. Ultimately, recruitment concluded in October 1999 having only recruited a total sample of 346 women. The many impediments to recruitment are summarized below. In addition, there was a high rate of attrition between collection of the baseline and follow-up data as we were only able to relocate 60% of our baseline sample. This is most likely associated with the overall low socioeconomic status of our target audience. Indeed, among women reporting income in the final survey, 53% had household

incomes under \$20,000, indicating that we did reach the underserved population targeted.

In the annual report covering the 2nd project year, July 1, 1997 - June 30, 1998, we identified a number of difficulties with the outreach model and corrective action was underway. Recruitment at that time had improved. However, this improvement proved to be short-lived. The sections that follow summarize:

- difficulties that then lead to a suspension of the trial in mid-October 1998;
- modifications made to the outreach protocol as a result; and
- accomplishments in an updated Statement of Work.

The modified protocol was pilot-tested, deemed feasible based on increased enrollment, and the trial resumed on December 8, 1998.

### (ii.) Summary of Problems Leading to Suspension of Trial

Agency Recruitment. We experienced considerable difficulty in agency recruitment (volunteers were to be recruited in teams of 4, each team being associated with a business, volunteer group, or other naturally occurring "agency"; teams were then randomized to intervention or control). We believed that additional staff training, focusing on ideal characteristics of prospective volunteer agencies, expansion of the geographic regions being targeted, and communication regarding the randomization process as well as modification to the agency criteria (groups greater than 4 were permitted as well as smaller groups, which were then combined and randomized as an agency unit) had resolved these problems. At the time the trial was suspended, 58 volunteers had been randomized to intervention (these were "Women's Health Leaders" or WHLs) and 26 were randomized to control (CILs or "Community Information Leaders"). The reason for the imbalance is that an equal number of teams had been randomized, but intervention agencies tended to have more volunteers per team. However, the modification to the protocol (described below) improved this balance consierably. Our fundamental problems thereafter were not with agency recruitment (although this was still an intensive process since 366 agencies were ultimately contacted). Rather, the problems related to training and motivation of volunteers who agreed to participate.

Training. One of the major costs in the original BACCIS was the intensive and ongoing training that was required to keep paid outreach workers functioning at a high level of effectiveness. The plan for BACCIS-II was to reduce training to a minimum, but at a level still sufficient to equip women with the basic information and skills needed. This produced limited results and in the middle of 1998, our field staff (known as Community Educators - CEs) had begun going into the field with volunteers to personally demonstrate the elements of outreach. This proved effective, but when the CEs stopped going into the field with volunteers (late August and September), the rate of recruitment fell off precipitously. We could not continue the practice of CEs in the field since that was too similar to the original BACCIS model. It is becoming clear that, just as women in underserved communities need ongoing support to continue getting mammograms, volunteers need ongoing support to continue finding and working with those women.

Volunteer Motivation/Incentives. Our original plan for volunteer incentives called for intervention teams to receive \$500 for recruitment and yearlong follow-up with 80 women per agency. Control teams would receive \$50 for recruitment only of 80 women per agency. Recruitment for both groups consisted of identifying qualified women (ages 45+ and no mammogram in the past two years) and completion of a baseline survey, self-administered by the respondent. In addition, volunteers in the intervention arm were to follow up with women according to our outreach protocol and, for the purpose of assessing cost for our cost-effectiveness analysis, were asked to complete a simple one-page follow-up form after each contact. This was designed to permit measurement of the time spent with each woman and the result of the contact. However, this task and management of the baseline survey proved onerous to women unaccustomed to such paperwork even though we tied completion of the first follow-up form to receipt of incentives, which were distributed in \$10 increments, upon receipt of two baseline surveys and one follow-up form per woman recruited. (Additional incentives were to be paid for completion of follow-up). Submission of follow-up forms was inadequate, although it was greatly improved and more consistent since the change in protocol at the end of 1998.

A second problem was the even slower recruitment of study participants into the control group (women who completed a baseline survey and received printed information on mammography but no personal follow-up) due to the very small monetary incentive to control group volunteers.

### (iii.) Modifications to Protocol

With the disappointing enrollment in August and September 1998, the trial was suspended and staff set about devising adaptations to the protocol that would retain the integrity of the study design but eliminate the most problematic obstacles to outreach. Thus, the following modifications were pilottested in October and November:

### 1. Elimination of volunteer responsibility for baseline survey.

Under the modified protocol, volunteers became only responsible for identification of eligible women and obtaining the women's permission to relay their names and phone numbers to BACCIS staff who then called the women and administered the baseline survey over the phone. The task of requesting completion of the baseline survey was difficult for all our volunteers, and more so for the less acculturated and less educated Latinas. In particular, staff were better able to administer the consent form and respond to questions regarding informed consent. Following completion of the consent and survey by phone, a copy of the consent form was mailed to every respondent.

Identification of at-risk women is the most time-consuming element of the outreach process, and if this could feasiblely be done by volunteers working in conjunction with paid staff, the model might have still proved more cost-effective than the more intensive model. For every name who proved eligible and willing to participate, the volunteers (renamed "Links"... to the community), received an incentive of \$5. Once a "Link" became active (referred the first eligible woman), she was randomized and all women referred by her go into the appropriate study arm. Thus, as before, randomization was by volunteer, not by participating respondent.

### 2. Elimination of follow-up responsibility.

A key element in encouragement of periodic screening among underserved women is establishment of a relationship that is maintained over time and involves the expression of concern and support around getting annual mammography. Because this involves following a protocol, simple though it is, and some record-keeping, this too was overly time-consuming for the amount of compensation offered and difficult for many volunteers. Thus, this responsibility was also turned over to BACCIS staff for women in the intervention arm only. This change did not affect the overall evaluation design, but did have an impact on the cost of the intervention.

### 3. Modification of sample size.

Our plan following the modifications was to continue the trial until we enrolled 500 women. As described in detail in an earlier report, only 120 women per study arm are needed to adequately power an evaluation of the effectiveness of the intervention. (As our results now indicate, we can show a significant intervention effect with even fewer women due to the strength of the intervention). However, since a primary concern was the cost-effectiveness of the intervention, we wanted to have adequate time to assess costs in relation to effectiveness for the new protocol. Because we knew it would take longer than originally planned to complete the intervention, we planned to continue our evaluation, analyses and reporting into a fifth year, a no-cost-extension which has just concluded. We had aimed to complete recruitment of the sample by mid-December 1999. Thus, the last women enrolled would have received their final evaluation interviews by February 2001 (14 months following the baseline survey, to allow time for one mammogram and then potentially a second). As already indicated, due to difficulties in locating women, we continued attempting to track participants until funds were no longer available. As a result, most of our analyses remain to be done and results provided in this report are preliminary.

The significant modifications made to the protocol did not result in an adequate improvement in recruitment, although we continued renewed attempts to increase recruitment throughout most of 1999. Prior to the cessation of the trial, average recruitment was 20 women per month. This only picked up to 24 women per month in the six months following resumption of the trial, dropping off again to approximately 6 women per month in the last six months of recruitment. This is despite the fact that recruitment of volunteers (who in turn recruited study participants) far exceeded our original goals. A total of 214 volunteers were recruited (115 in the intervention group and 99 control). The original goal was to recruit 160. However, only 59 volunteers were active, meaning they recruited at least one eligible study participant. In the intervention group, active volunteers recruited an average of 6.3 women and active control volunteers recruited an average of 5.3 women. This compares with the original goal of 20 women per volunteer.

### (iv.) Results

<u>Baseline survey results</u>. The baseline survey instrument is Appendix A. Baseline characteristics are shown in Table 1. (In an effort to keep the baseline survey very brief and simple for self-administration according to the original plan, information on income and education was not collected until the final survey). Twenty-seven percent of the sample was

African American, 52% Latina, 16% non-Hispanic white, and 5% other race/ethnicity. Overall, fifty-one percent reported having no health insurance. The intervention group had more African Americans and the control group more Latinas. As a function of these factors, the control group was more insured and had more women who had ever had a mammogram.

Table 1. Baseline Characteristics (n = 346)

	Intervention (n=225)	Control (n=121)
Mean Age	57	60
Race	%	%
African American	16	47
Latina	68	21
White	11	25
Other	4	7
No Health Insurance	65	26
Ever had a mammogram	69	79
Years since last mammogram		
2 - 5	48	50
6+	9	14
Don't know	3	6
Never	40	30

<u>Intervention data.</u> Among the 225 women in the intervention group, 193 received follow-up counseling by phone by the staff Community Educators. This involved encouragement to get a mammogram, resources on how to obtain screening, and calls to remind or check on appointments.

Final survey results. The final survey instrument is Appendix B. We were able to locate 208 women from the baseline sample (60%) to complete the final survey which was administered by staff over the phone. Thirty percent of women in the baseline sample were re-interviewed 14 to 16 months following completion of the baseline survey; 62% were surveyed 17to 24 months post-baseline, and 7% were interviewed 25 or more months following baseline. Table 2. shows the demographic characteristics of the women in the final survey. The age and race/ethnic distribution of those in the final survey is very similar to the baseline. However, far more women in the baseline sample were uninsured. While there was a high proportion of low-income women in the final survey, it is likely that more still were lost to follow-up due to more transiency.

### The main outcomes include:

- 1. In the intervention group, 82% of women (131) had a mammogram since baseline compared with 67% of women in the control (p=.02).
- 2. Sixty-eight percent of women in the intervention group responded that they recalled being called by someone from the BACCIS program within the past 12 months (the follow-up counseling by staff CEs) compared with 22% of controls (p < 0.0001).
- 3. Forty-two percent of women in the intervention group reported trying to get a free mammogram (through state or federally funded programs, a recommendation of CEs) compared with 11% of controls (p=0.0001).

Among final survey respondents who reported income (n=141, 68%), there were significantly more women in the intervention group reporting income under \$20,000 compared with those in the control group (p<.05). Thus, not only was the intervention effective at increasing use of mammography, but this was the case among more underserved women.

For women in the intervention group, staff CE's completed a form for each contact whether by phone or in person. This data set indicates both the amount of contact between staff and participants but also the progress of women in the intervention group. In the course of these follow-up contacts, staff reported that 116 women in the intervention group received at least one mammogram during the intervention period and that 38 of these women received two mammograms. Thus, 20% of women 50+ in the intervention group received two mammograms. This repeat screening was the ultimate goal of the intervention.

Table 2. Characteristics of Women Completing the Final Survey (n = 208)

	Intervention	Control
Mean Age	57.1	59.0
Race	%	%
African American	17	46
Latina	71	20
White	9	26
Other	3	8
No Health Insurance	42	13
Income		
<\$20,000	43%	31%
20,000+	24	37
Don't know/refused	33	31
Education (years of schooling)		
<12 years	57%	30%
12 years	13	20
>12 years	22	48
Don't know/refused	8	3

### B. Technical Objectives: Evaluate cost-effectiveness of three levels of intervention

A draft manuscript on the CEA for BACCIS-I is currently on hold due to recent analyses showing little intervention effect in that trial due to contamination of the control group from community-based screening initiatives outside the study. Further analyses are underway and upon their completion, the viability of comparing BACCIS-I and BACCIS-II will be assessed.

This makes all the more compelling our plans for a manuscript that discusses the issues involved in evaluating the costs and effectiveness of community-based interventions such as BACCIS-I and BACCIS-II. We have learned a great deal about the challenges involved in evaluating interventions and approaches to overcome them, so that these "lessons learned" can be applied to future interventions.

It is evident that, due to the difficulty in recruiting women into the study, the moderate level intervention has proved infeasible and not cost-effective. This finding will be reported in the main outcome paper.

# III. Summary of Accomplishments Associated with Each Task from Approved Statement of Work

Technical Objectives: To test the feasibility and effectiveness of a moderate intensity outreach intervention

<ul> <li>Task (as Originally Proposed)</li> <li>1. Adapt/pre-test BACCIS model</li> <li>2. Develop/pre-test baseline survey</li> <li>3. Recruit 20 businesses/agencies/organizations (intervention arm numbers only)</li> <li>4. Train 80 Women's Health</li> </ul>	complete complete reduced to 15/ complete complete complete
	99 trainees in control group)

Enrolled 346; intervention follow-up completed for 198 women

Follow-up ended March 2001

5. Enroll & follow-up 1600 women

in the intervention group

final survey completed for 208 women

in progress

7. Complete process evaluation

analyses by month 43

6. Complete final survey of 3200 women by month 43

Technical Objectives: Evaluate cost-effectiveness of three levels of intervention Task (as Originally Proposed)

9. Research relevant literature

complete

complete 10. Develop cost-effectiveness analysis design

11. Develop data collection approaches

complete

12. Monitor collection of intervention cost data and effectiveness data and instruments

complete

13. Develop analytic model and input

in progress

in progress 14. Complete societal and organizational

analyses and reporting

1

### III. Key Research Accomplishments and Reportable Outcomes

- Recruitment into the trial and follow-up are completed, albeit with very disappointing results.
- These results are an important indication that a moderate intensity intervention to reach underserved women may not be feasible.
- Despite the fact that recruitment was low, the woman to woman approach to outreach and followup appears once again to effectively increase screening rates in underserved communities.
- While none of the three interventions appear to optimize cost and effectiveness (BACCIS-I due to very high costs and non-significant results, BACCIS-II moderate intensity intervention due to high costs associated with low feasibility, and BACCIS-II minimum intensity intervention due to low effectiveness), we will document the costs and effectiveness of these interventions to serve as benchmarks for other interventions. This will be an important contribution to the literature on screening outreach.

### IV. Conclusions

We can now draw one preliminary conclusion regarding the feasibility of the intervention: Outreach to underserved women using lay health workers is time-consuming and costly. There may be no way to streamline recruitment and education of women through this mechanism. Furthermore, intensive and ongoing support of lay health workers is required and modest monetary incentives do not compensate for lack of such support and training. Thus, the search for cost-effective means of bringing underserved women into screening must continue.

Other preliminary conclusions address the complexity of conducting randomized clinical trials in underserved communities:

- Personal contact through trusted others is effective in motivating and assisting underserved women to obtain initial and repeat screening.
- Continued research is needed to identify feasible alternatives to the costly use of paid outreach workers.

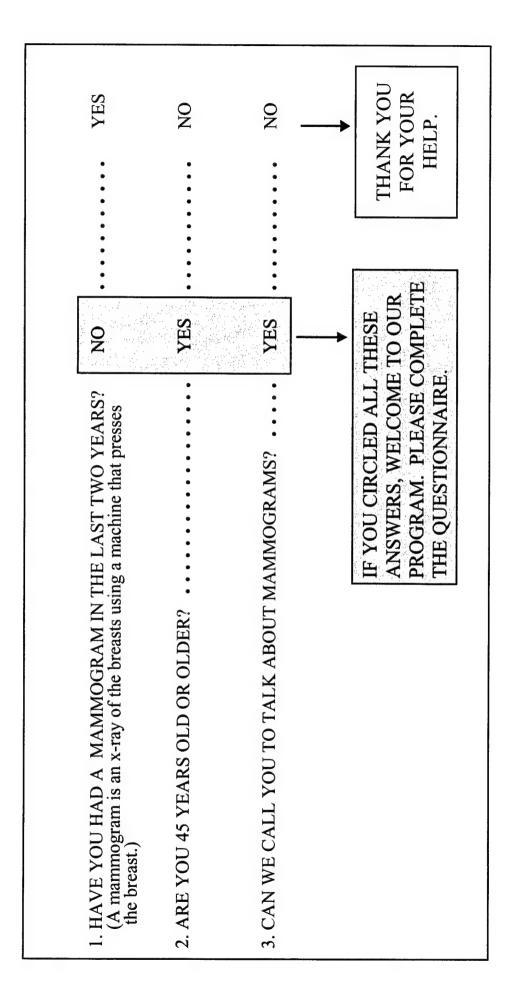
Toward this end, we are currently conducting a National Cancer Institute funded study that adapts this methodology considerably, still in the effort to reduce costs while maintaining personal contact. In this study, a cohort of 1465 women has been recruited at random by phone in Alameda County (499 African American, 199 Chinese, 167 Filipino, 300 Latino, and 300 non-Hispanic white). Half are randomized to the intervention group who receive computer tailored mailings and telephone counseling from trained, paid lay health workers. While this is a more costly intervention than the moderate level proposed for BACCIS-II, it is less costly than the intensive intervention of BACCIS-I. Thus far we have been far more effective in training and retaining lay health workers and the counseling appears to quite effective. Furthermore, we have taken intensive steps to maintain our

cohort over time (through recruitment of women who could be re-contacted readily at baseline and through payment for each survey) and were able to re-interview 89% of our sample after one year for the second of three surveys.

Appendix A.

**Baseline Survey** 

## CONTRA COSTA WOMEN'S HEALTH QUESTIONNAIRE



## THANK YOU FOR YOUR TIME!!!

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SACCIS VOLUNTEER PLEASE COMPLETE:	
YOUR NAME. DATE.	BACCIS ID#

WHY HAVEN'T YOU HAD A MAMMOGRAM IN THE LAST TWO YEARS?

	☐ My doctor didn't tell me to get one	st one	Mammogram x-rays are dangerous
	I don't need it at my age		A mammogram might hurt or be uncomfortable
	I am worried about the cost		I didn't like the mammogram I got before
	☐ I don't have insurance		I am afraid of finding something wrong
	I'm too busy to get a mammogram	gram	It is embarrassing to have that kind of exam
	I don't have a doctor		I don't need a mammogram because I'm healthy
	☐ I don't have a place to go		Doctors don't understand women of my race
	I don't have a way to get there	O	I am worried that the x-ray technician might be a man
	☐ I have no one to take care of my children	ny children	I forgot to make an appointment
	The appointment takes too long	gı	☐ My husband doesn't want me to
	☐ The doctor doesn't speak my l	language	Getting a mammogram is just too much trouble
	I need a translator		Other reason (Please Explain):
	☐ I'm just not worried about breast cancer	ast cancer	
5.	Before today, had you ever heard of a mammogram?	l of a mammogram?	□ YES □ NO
9.	Have you <u>ever had</u> a mammogram?	n?	
	□ YES	If YES:	
		Then did you have yo	mammo
	ON	)W ——— W(	MONTH YEAR YEAR
		low many manninggr NU	now many manninggrams have you had in the tast 3 years?  NUMBER OF MAMMOGRAMS
7.	Do you plan to have a mammogram in the next 12 months?	am in the next 12 mc	nths?

3#	FERSON S INAME
$(T_{k-1}, t_{k-1}, t_{k-1}, \dots, t_{k-1}, t_{k-1$	'ERSON'S PHONE #
V hat 1s this person's relationship to voil?	

## THANK YOU FOR YOUR HELP!

Appendix B.

Final Survey

### Information for BACCIS Participants

•
Hello Mrs./Ms./Miss I am calling from BACCIS, the women's health program in Contra Costa County. You may remember filling out one of our surveys just about one year ago. Thank you very much for your involvement in our program.
I am calling today to ask you to complete one more 10 to 15 minute survey by phone that will help us learn how the women we have reached are doing. Your assistance is especially important because this program is trying to help women learn more about cancer screening. This survey is the last part of our program.
First, I would like to tell you about your rights as a participant in this survey. This is strictly voluntary. You may refuse to answer any questions. No medical care or other services are dependent on your participation. The information you provide will be strictly confidential. Your name will not be used in connection with this information or given to anyone outside our program. All personal information will be kept in a locked case with names deleted. There is no risk to you from your participation in this program. However, the federal government agency who is our sponsor has a rule that we must inform you that any injury that happens to you because of your participation will be paid for.
There are no costs to you for participating in this program. However, you will benefit by helping us to learn more about the health needs of women in your community so that better programs can be developed.
I am going to mail you a copy of this information for your records. If you would like more information, you may contact: Dr. Rena Pasick Northern California Cancer Center, 32960 Alvarado-Niles Rd., Suite 600 Union City, CA 94587 (510) 429-2500
Also, information about your rights as a program participant can be obtained from: NCCC IRB Chairman Anthony Ubalde Northern California Cancer Center, 32960 Alvarado-Niles Rd., Suite 600 Union City, CA 94587 (510) 429-2500
Project Title: Breast Cancer Outreach for Underserved Women: A Randomized Trial and Cost-Effectiveness Analysis
Participant Name:
(Please Print)
Read over telephone: Staff initials Date

### **BACCIS-II Final Survey**

1.	Woman's name	/ ID#
	Interviewer Initials:	Date of Interview:
	May I begin my questions?	
2.	Before today, have you ever heard of a may of the breasts using a machine that pressed 1. Yes 2. No 7. [DON'T READ] NOT APPLICABLE 8. [DON'T READ] DON'T KNOW/NOT 9. [DON'T READ] REFUSED	es the breast).
3.	Have you ever had a mammogram?  1. Yes  2. No  7. [DON'T READ] NOT APPLICABLE  8. [DON'T READ] DON'T KNOW/NOT  9. [DON'T READ] REFUSED	
YE	ow long ago did you have your last mammodARS (2 digits: 01, 02, etc.) (Less that	in one year = 00)
	NTHS (01-12)	MART MORTHOJ.
b. How m	any mammograms have you had in the last	5 years?
c. Was yo	E PAST YEAR]: our last mammogram normal, or did you hav Normal  [GO TO 4]	ve to have more tests?
2. 7. 8.	More tests [DON'T READ] NOT APPLICABLE [DON'T READ] DON'T KNOW/NOT SURE [DON'T READ] REFUSED	
1. 2. 3. 6. 7. 8.	TESTS]; vas the result of those tests? [DON'T READ] CANCER [DON'T READ] CANCER SUSPECTED [DON'T READ] BENIGN (NO PROBLEM) [DON'T READ] OTHER [SPECIFY]: [DON'T READ] NOT APPLICABLE [DON'T READ] DON'T KNOW/NOT SURE [DON'T READ] REFUSED	

- 4. Do you plan to have a mammogram in the next 12 months?
  - 1. Yes-
  - 2. No [GO TO Q5]
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED

### [If YES]:

- 4a. Do you plan to continue having a mammogram every year?
  - 1. Yes [GO TO Q5]
  - 2. No **[GO TO Q5]**
  - 7. [DON'T READ] NOT APPLICABLE [GO TO Q5]
  - 8. [DON'T READ] DON'T KNOW/NOT SURE [GO TO Q5]
  - 9. [DON'T READ] REFUSED [GO TO Q5]
- 5. Do you know where to go if you wanted a mammogram this month?
  - 1. Yes
  - 2. No
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED
- 6. Have you ever had a breast exam by a doctor or nurse? A breast exam is when a doctor or nurse feels for lumps in your breasts?
  - 1. Yes —
  - 2. No **[GO TO Q. 7]**
  - 7. **[DON'T READ]** NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED

[IF YES]:
6a. About how long ago did you have your last breast exam?  Years (Less than one year = 00) (2 digit year code)
[IF LESS THAN ONE YEAR, RECORD HOW MANY MONTHS]: Months (01-12)

- 7. Is there one doctor that you usually see when you are sick or need a check up?
  - 1. Yes
  - 2. No
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED
- 8. My next questions are things people sometimes say about mammograms. These are opinions and there are no right or wrong answers. Please tell me if you agree or disagree?
- a. You don't need a mammogram if you've had a breast exam from a doctor or a nurse. Do you agree or disagree with that statement?
  - 1. Agree
  - 2. Disagree
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED
- b. Mammograms can lead to breast surgery that is not needed.
  - 1. Agree
  - 2. Disagree
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED
- c. You would have a mammogram if your doctor told you that it's important.
  - 1. Agree
  - 2. Disagree
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. **[DON'T READ]** REFUSED
- d. You won't have a mammogram if it takes more than an hour to get there. Do you agree of disagree with that?
  - 1. Agree
  - 2. Disagree
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. **IDON'T READI** REFUSED
- e. Having a mammogram every year will give you a feeling of control over your health.
  - 1. Agree
  - 2. Disagree
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED

- f. You will only get a mammogram if you have a breast problem.
  - 1. Agree
  - 2. Disagree
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED
- g. Mammograms are a very common medical test.
  - 1. Agree
  - 2. Disagree
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED
- i. It will be good for your family if you have a mammogram.
  - 1. Agree
  - 2. Disagree
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED
- j. Regular mammograms give you peace of mind about your health.
  - 1. Agree
  - 2. Disagree
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED
- k. A mammogram is just a good way to take care of yourself.
  - 1. Agree
  - 2. Disagree
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED
- I. A woman should get a mammogram even if there is no breast cancer in her family.
  - 1. Agree
  - 2. Disagree
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED
- m. Mammograms work best when you have one every year.
  - 1. Agree
  - 2. Disagree
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED

- n. Mammograms are safe.
  - 1. Agree
  - 2. Disagree
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED
- o. You are too busy to have a mammogram.
  - 1. Agree
  - 2. Disagree
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED
- p. Do you agree or disagree with this statement:

A mammogram is not a useful test for women your age.

- 1. Agree
- 2. Disagree
- 7. [DON'T READ] NOT APPLICABLE
- 8. [DON'T READ] DON'T KNOW/NOT SURE
- 9. [DON'T READ] REFUSED
- q. Mammograms cost too much for you.
  - 1. Agree
  - 2. Disagree
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. **[DON'T READ]** REFUSED
- r. A mammogram might hurt or be uncomfortable.
  - 1. Agree
  - 2. Disagree
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. **[DON'T READ]** DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED
- s. You're just not worried about breast cancer.
  - 1. Agree
  - 2. Disagree
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED
- t. You don't need a mammogram because you're healthy. Do you agree or disagree with that?
  - 1. Agree
  - 2. Disagree
  - 7. **IDON'T READ!** NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED

- u: Getting a mammogram is just too much trouble.
  - 1. Agree
  - 2. Disagree
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED
- v. Do you agree or disagree that:

You don't need a mammogram at your age.

- 1. Agree
- 2. Disagree
- 7. [DON'T READ] NOT APPLICABLE
- 8. **[DON'T READ]** DON'T KNOW/NOT SURE
- 9. [DON'T READ] REFUSED

- 9. During the past 12 months, has anyone from our BACCIS program talked to you about getting a mammogram? (Someone who might have given you the white, flat, magnetic BACCIS pen or sent it to you in the mail? Also, someone might have called from our program...do you recall that?)
  - 1. Yes
  - 2. No **[GO TO Q10]**
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED

### [If YES]:

- a. Did you like talking to that person?
  - 1. Yes
  - 2. No
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED
- b. Was she helpful to you?
  - 1. Yes
  - 2. No
  - 7. **[DON'T READ]** NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. **[DON'T READ]** REFUSED
- c. Did she convince you to get a mammogram?
  - 1. Yes
  - 2. No
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. **[DON'T READ]** REFUSED
- 10. During the past 12 months, has any <u>other</u> woman you know talked to you about getting a mammogram?
  - 1. Yes
  - 2. No **[GO TO Q11]**
  - 7. [DON'T READ] NOT APPLICABLE [GO TO Q11]
  - 8. [DON'T READ] DON'T KNOW/NOT SURE [GO TO Q11]
  - 9. [DON'T READ] REFUSED [GO TO Q11]

- a. Was she a volunteer with our program?
  - Yes\_\_\_
  - 2. No **[GO TO Q11]**
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE\_
  - 9. [DON'T READ] REFUSED [GO TO Q11]

### [If YES or NOT SURE]:

- b. Did she convince you to get a mammogram?
  - 1. Yes
  - 2. No
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED
- 11. During the past 12 months have you tried to get a free mammogram? (Free means no charge at all, not the same as covered by insurance)
  - 1. Yes \_\_\_\_
  - 2. No **[GO TO Q12]**
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED

### [If YES]:

- 11a. Were you eligible (able to get the mammogram for free)?
  - 1. Yes
  - 2. No [ASK 11b.]
  - 7. **[DON'T READ]** NOT APPLICABLE
  - 8. **[DON'T READ]** DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED

[If NO]:

- 11b. What was the reason? (Select ALL THAT APPLY)
  - 1. [DON'T READ] Age
  - 2. [DON'T READ] Income
  - 3. [DON'T READ] Other (SPECIFY): \_\_\_\_

- 12. These are questions about health insurance. Please answer yes or no for each choice. Do you have:
  - a. Medicare (This is a health plan from the government to pay for medical expenses for people 65 and older, or people with a disability)
    - 1. Yes
    - 2. No
    - 7. [DON'T READ] NOT APPLICABLE
    - 8. [DON'T READ] DON'T KNOW/NOT SURE
    - 9. [DON'T READ] REFUSED
  - b. MediCal (This is a health plan from the state government to pay for medical expenses for people with low income or a disability)
    - 1. Yes \_\_\_
    - 2. No.
    - 7. **[DON'T READ]** NOT APPLICABLE
    - 8. [DON'T READ] DON'T KNOW/NOT SURE
    - 9. [DON'T READ] REFUSED

### [If YES to MediCal]

Do You Have:

- (i) Contra Costa Health Plan
  - 1. Yes
  - 2. No
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED
- (ii) Blue Cross Health Plan
  - 1. Yes
  - 2. No
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED

Do you have:

<ul><li>c. Health insurance that you, your family, or your employer pays for?</li></ul>
<ol> <li>Yes [Name of Company:]</li> <li>No</li> <li>[DON'T READ] NOT APPLICABLE</li> <li>[DON'T READ] DON'T KNOW/NOT SURE</li> <li>[DON'T READ] REFUSED</li> </ol>
d. Basic Adult Care (BAC from Contra Costa County)
<ol> <li>Yes</li> <li>No</li> <li>[DON'T READ] NOT APPLICABLE</li> <li>[DON'T READ] DON'T KNOW/NOT SURE</li> <li>[DON'T READ] REFUSED</li> </ol>
e. [If ALL Nos to 12a through d] According to everything you have told me, you do not have health insurance of any kind. Not including dental or vision care, do you have health insurance that pays for doctor visits through a plan that I might have missed?  1. Yes [Name of Company:] 2. No 7. [DON'T READ] NOT APPLICABLE 8. [DON'T READ] DON'T KNOW/NOT SURE 9. [DON'T READ] REFUSED
13. When you go to the doctor, do you have to pay with your own money? (This means full payment, does not include co-pay.)
<ol> <li>Yes</li> <li>No</li> <li>[DON'T READ] NOT APPLICABLE</li> <li>[DON'T READ] DON'T KNOW/NOT SURE</li> <li>[DON'T READ] REFUSED</li> </ol>

I just have a few more questions. 14. In what country were you born? [CODE BUT DO NOT READ] 1. United States [SKIP TO 15] 2. Mexico Cuba 3. El Salvador 4. 5. Colombia Argentina 6. 96. Other [SPECIFY]: 97. [DON'T READ] NOT APPLICABLE 98. [DON'T READ] DON'T KNOW/NOT SURE 99. [DON'T READ] REFUSED 14a. How old were you when you first came to live here in the United States? Age of arrival (If less than 1 year, code - 0. Logical range = 1-90) 97. [DON'T READ] NOT APPLICABLE 98. [DON'T READ] DON'T KNOW/NOT SURE 99. [DON'T READ] REFUSED 14b. In total, how many years have you lived in the United States? Years (If less than 1 year, code = 0. Logical range = 1-90) 97. [DON'T READ] NOT APPLICABLE 98. [DON'T READ] DON'T KNOW/NOT SURE 99. [DON'T READ] REFUSED 15. In general, what language(s) do you speak? [Choose all that apply] [CODE BUT DO NOT READ] 1. English \_\_\_\_\_

Spanish

3. Other [SPECIFY]:

### [If speaks language other than/in addition to English]:

- 15a. How well do you speak English?
  - 1. Fluently, like a native
  - 2. Well
  - 3. So-So
  - 4. Poorly
  - 5. Not at all
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED
- b. In general, what language(s) do you read?
  - 1. English only
  - 2. English better than Spanish (other language)
  - 3. Both equally
  - 4. Spanish (or other language) better than English
  - 5. Only Spanish (other language)
  - 6. Other (SPECIFY):
  - 7. **[DON'T READ]** NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. **[DON'T READ]** REFUSED
- c. What language(s) do you usually speak at home?
  - 1. English only
  - 2. English more than Spanish (other language)
  - 3. Both equally
  - 4. Spanish (or other language) more than English
  - 5. Only Spanish (other language)
  - 6. Other (SPECIFY):
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED
- d. What language(s) do you usually speak with your friends?
  - 1. English only
  - 2. English more than Spanish (other language)
  - 3. Both equally
  - 4. Spanish (or other language) more than English
  - 5. Only Spanish (other language)
  - 6. Other (SPECIFY):
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED

16. How many years of school did you finish?

### IF Respondent says [grade level], Code as follows:

Elementary = 6; Junior High = 8; High School/GED = 12; Some college/Vocational School =14; College Graduate = 16; Master's Degree = 18; MD, PhD, JD, DDS = 20

Years

- 17. Do you own your home?
  - 1. Yes
  - 2. No
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED
- 18. In total, including yourself, how many people live in your household?

\_\_\_\_ Number of Persons

- 97. [DON'T READ] NOT APPLICABLE
- 98. [DON'T READ] DON'T KNOW/NOT SURE
- 99. [DON'T READ] REFUSED
- 19. These are my last questions. Now I am going to ask you about your household income. It may be hard to estimate this income, but do your best. This information will be strictly confidential. Taking all the income of all the members of your household, which of these categories best fits your total household income for last year (1999)? Is it:

(**OPTIONAL** - Income includes: wages, Social Security, retirement or pensions, unemployment benefits and disability)

- 1. Less than \$5000
- 2. \$ 5,000 to less than 10,000
- 3. \$10,000 to less than 20,000
- 4. \$20,000 to less than 30,000
- 5. \$30,000 to less than 40,000
- 6. \$40,000 to less than 50,000
- 7. \$50,001 or more
- 97. [DON'T READ] NOT APPLICABLE
- 98. [DON'T READ] DON'T KNOW/NOT SURE
- 99. [DON'T READ] REFUSED
- 20. Are you receiving SSI (Supplementary Security Income or the gold check)?
  - 1. Yes
  - 2. No
  - 7. [DON'T READ] NOT APPLICABLE
  - 8. [DON'T READ] DON'T KNOW/NOT SURE
  - 9. [DON'T READ] REFUSED

That's the end of my survey, but I'd like to know if: 21. You need any help to get a mammogram now? 1. Yes -2. No 7. **[DON'T READ]** NOT APPLICABLE 8. [DON'T READ] DON'T KNOW/NOT SURE 9. [DON'T READ] REFUSED 21a. [If YES:] Shall I have one of our staff call you in the next couple of weeks? 1. Yes 2. No 7. **[DON'T READ]** NOT APPLICABLE 8. [DON'T READ] DON'T KNOW/NOT SURE 9. [DON'T READ] REFUSED Thank you very much for completing these questions. 22. Would it be alright if we contact you again sometime for another survey? 1. Yes 2. No 7. [DON'T READ] NOT APPLICABLE 8. [DON'T READ] DON'T KNOW/NOT SURE 9. [DON'T READ] REFUSED Thank you again for your time.

Interviewer comments:		
	Interviewer	Date

Appendix C.

**Presentation Abstract** 

### Challenges in Breast Cancer Outreach to the Underserved

Pasick RJ, Stewart SL, Phillips K, and Davis P. Northern California Cancer Center

Presentation to the Era of Hope DOD Breast Cancer Research Program.

June 9, 2000

Atlanta, Georgia

### Scientific Abstract

Current practices in breast cancer outreach to underserved communities lack interventions that address periodic screening and have been shown to be cost-effective. Based on a previous study (the Breast and Cervical Cancer Intervention Study - BACCIS) in which outreach was effective but intensive and costly, the current study (BACCIS-II) developed a moderate intensity model that is being evaluated for cost-effectiveness in a randomized controlled trial with a minimal intervention. These will be retrospectively compared with the original BACCIS intervention.

The original BACCIS model involved full-time paid outreach workers who recruited women from low-income communities of the San Francisco Bay area, and established ongoing relationships to encourage initial and repeat screening. Pivotal factors were the personal bond between outreach workers and women, including continued support over time. However, the practicality of such an approach is questionable. In the new model, volunteers, rather than paid staff, recruited women ages 45+ who had not had a mammogram in the past two years. They obtained answers to a brief baseline survey, and used the personal approach to encourage initial and repeat mammography over a period of one year. A financial incentive was offered based on number of women recruited. For the control group (the minimal intervention) volunteers were asked only to identify women by the same criteria, obtain the baseline survey, and provide printed material on mammography, and received a smaller incentive. All enrolled women are re-interviewed by phone one year after the baseline survey to assess changes in mammography use and intentions. Recruitment concluded November 1999. The personal follow-up continues for women recruited less than one year ago, and the final telephone survey of women recruited more than one year ago is ongoing.

Recruitment of volunteers was far more challenging than anticipated despite repeated protocol modifications, ultimately reducing volunteer commitment to only identification of women meeting eligibility criteria (staff then completed the baseline survey and outreach follow-up by phone). In addition, volunteers found it difficult to identify women who meet the criteria. A total of 214 volunteers were recruited (115 intervention; 99 control). They enrolled 230 women for intervention and 123 controls. Once identified and followed up, to date 47% (108 out of 230) of women in the intervention group have received one mammogram; 6% of those have had two. (Control group data will be available upon completion of the final survey). Results to date indicate that there may be no feasible alternative to the costly use of paid outreach workers.

Supported by the US Army Medical Research & Materiel Command/ DAMD 17-96-1-6070.

Appendix D.

List of Personnel Supported by this Grant

### PERSONNEL SUPPORTED BY THIS GRANT

Rena J. Pasick, Dr.P.H. - Principal Investigator

Susan L. Stewart, Ph.D. - Co-Investigator (Biostatistics)

Kathryn Phillips, Ph.D. - Co-Investigator (Health Economics)

Jocelyn Koo - Statistician/Programmer

Patricia Davis, MPH - Program Manager

Wanna Wright - Community Educator

Mirna Alvarado - Community Educator

Mary Sue Weston - Administrative Assistant